

## 510(k) Summary for SOMATOM Perspective

**Company:** Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway  
Malvern, PA 19355

**Date Prepared:** May 21, 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

### 1. Contact Person:

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### 2. Device Name and Classification:

Product Name: SOMATOM Project P68  
Proprietary Trade Name: SOMATOM Perspective  
Classification Name: Computed Tomography X-ray System  
Classification Panel: Radiology  
CFR Section: 21 CFR §892.1750  
Device Class: Class II  
Product Code: 90 JAK

### 3. Substantial Equivalence:

Siemens SOMATOM Perspective Computed Tomography X-ray system, configured with software SOMARIS/5 is substantially equivalent to the following medical device in commercial distribution:

<b>Predicate Device Name</b>	<b>FDA Clearance Number</b>	<b>FDA Clearance Date</b>
Siemens SOMATOM Emotion 16	K050297	03/01/2005

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## 4. Device Description:

Similar to the predicate device (Siemens SOMATOM Emotion 16 premarket notification K050297, clearance date 03/01/2005), Siemens SOMATOM Perspective is a Computed Tomography X-ray System, which features a continuously rotating tube-detector system and functions according to the fan beam principle. The system software is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

The SOMATOM Perspective system produces CT images in DICOM format, which can be used by post processing applications commercially distributed by Siemens and other vendors.

SOMATOM Perspective operates with software version SOMARIS/5 which is a Windows XP®<sup>1)</sup> based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

The key software new features for SOMATOM Perspective are iTRIM (Iterative Temporal Resolution Improvement Method) to improve the temporal resolution to a value of about 80% of that of conventionally reconstructed images, and ECO Mode (eMode) to increase the tube life by reducing the tube power.

The computer system delivered with the CT scanner is able to run such post processing applications optionally.

## 5. Indications for Use:

The Siemens SOMATOM Perspective system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes\* taken at different angles.

In addition the SOMATOM Perspective is able to produce additional image planes and analysis results by executing optional post-processing features, which operate on DICOM images.

For cardiac imaging, which is an option on the system, a new reconstruction algorithm (iTRIM - Iterative Temporal Resolution Improvement Method) is used. iTRIM improves the temporal resolution of cardiac CT images compared to conventional cardiac CT image reconstruction. Actual results obtained with iTRIM can vary depending on the particular clinical situation.

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The images and results delivered by the SOMATOM Perspective can be used by a trained physician as an aid in diagnosis.

(\*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

## 6. Substantial Equivalence:

Siemens believes that SOMATOM Perspective is substantially equivalent to SOMATOM Emotion 16 (premarket notification K050297, clearance date 03/01/2005).

The differences between SOMATOM Perspective and SOMATOM Emotion 16 are listed below:

	<b>Subject SOMATOM Perspective</b>	<b>Predicate SOMATOM Emotion 16 (P10)</b>
X-Ray Assembly Tube Max.Power	Dura 688-MV 55 kW	Dura 422-MV 50kW
Detector rows	64	16
Total number of detector channels	64x736	16x736
Measuring channels	64x1472	16x1472
Spiral scan performance - Pitch factor - Max. uninterrupted scan time	up to 1.5 100 sec	up to 2.0 100 sec
Software Image Reconstruction Algorithm	with iTRIM	without iTRIM
Software Scan Mode	with eMode	without eMode

The mechanical structures of both systems are same. Except for detectors and tube, most components are reused or with minor modification to improve the performance matching the 64 rows detectors.

## 7. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:

SOMATOM Perspective does not have significant changes in materials, energy source, or technological characteristics when compared to the

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predicate device. The intended use and fundamental scientific technology are similar to the predicate device; therefore Siemens believes that they are substantially equivalent to this predicate device.

## **8. Nonclinical Testing:**

Non clinical tests are conducted for SOMATOM Perspective during product development. This includes verification and validation testing as well as phantom testing. The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria.

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

## **9. General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device. Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

Ms. Kimberly Magnum  
Technical Specialist, Regulatory Affairs Submissions  
Siemens Medical Solutions, Inc. USA  
51 Valley Stream Parkway, G-01  
MALVERN PA 19355-1406

MAY 23 2012

Re: K113287  
Trade/Device Name: SOMATOM Perspective  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: April 20, 2012  
Received: April 23, 2012

Dear Ms. Magnum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

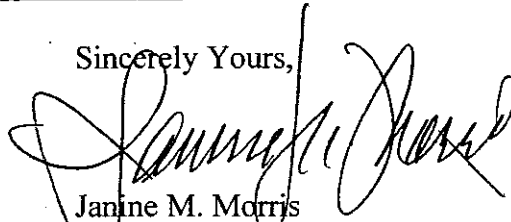
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris  
Acting Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

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## Attachment A Indications for Use

510(k) Number (if known): K113287

Device Name: **SOMATOM Perspective**

### Indications for Use:

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Prescription Use   X   AND/OR Over-The-Counter Use         
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
(Division Sign-Off)

Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113287